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Technical note

An automatic hinge system for leg orthoses

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Abstract

This paper describes a new automatic hinge system for leg orthoses, which provides knee stability in stance, and allows knee-flexion during swing. Indications for the hinge system are a paresis or paralysis of the quadriceps muscles. Instrumented gait analysis was performed in three patients, fitted with this new hinge system in a knee orthosis. The orthosis proves to satisfy the patients allowing them to walk without a knee-lock system

Introduction

An orthosis may be defined as a technical device that is attached to a part of the body to improve function, restrict or enforce motion, and/or to support a body segment. Lower limb orthoses are for instance indicated to reduce pain, to minimise worsening of a deformity, decrease weight bearing or as in this study, assist gait and/or control movement. Most orthoses do not assist the swing-phase and stance-phase in a way that the patient feels secure and most orthoses cannot give the natural appearance of normal gait.

This new knee hinge is specially and only designed in the case of patients with a paresis or paralysis of the quadriceps muscles. Medical indications are for instance femoral nerve damage, post-polio syndromes, multiple sclerosis, cerebral vascular accidents etc. Contraindications for this knee hinge are flexion contractures of the knee larger than 10°, spasms of the knee muscles, and contractures of the hip.

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In this paper the authors want to introduce a new kind of knee hinge, which provides knee stability in stance, and allows knee-flexion during swing and has been evaluated by instrumented gait analysis in three patients.

Knee hinge

The new knee hinge for orthoses derives its name (swing phase lock - SPL) from the moment the hinge locks during walking. As one of its kind, it is able to both automatically unlock after mid-stance, to allow knee flexion during late stance-phase and swing-phase as well as to lock just before initial (heel) contact. In other words, a knee hinge that is already locked before the user bears weight on it. A second quality of the SPL hinge is that it can only unlock when there is no flexion moment applied to the hinge. Characteristic for the SPL is that it can be used in knee orthoses and is therefore not dependent on the foot part/section or the axial pressure on the orthoses for detecting the moment to lock or unlock.



Fig. 1. SPL System; SPC (right), Suttehite (middle), SPL (left).

The SPL hinge is designed to be built into a KO, KAFO or HKAFO on the lateral side of the knee, supplemented by a free running knee hinge or a swing phase control (SPC) unit for the medial side. The hinges are provided with a common size connection for brace bars of 19mm wide and can therefore be applied in widely divergent orthoses concepts. This also makes it possible to test the hinge in already existing provisions with only a few adjustments.

The mechanism of the hinge

Different from other systems, the moment of locking/unlocking in the SPL is detected by an internal small mass that reacts to changes of the angle of the hinge in the sagittal field. The small mass can tumble in two positions and could be compared with an upside down pendulum. The position of the pendulum determines the moment the hinge can unlock or lock. It utilises the simple fact that seen from the hip the leg is in an

anteversion angle just before initial (heel) contact and moves to a retroversion angle after the mid-stance phase. For a pendulum this position is simple to detect. The hinge is locked when the hip is in flexion and the knee in extension, just before initial contact. During the locked situation the pendulum, that also acts as a blocking element, is pressed in its place by the flexion force on the hinge. It can only tumble to the other position when an extension moment is put on the hinge. This is the moment after the mid-stance phase when the extended knee falls behind the 'line of force'. In practice this means that two conditions must be met before the hinge can unlock. The hip must be in extension and with no weight bearing flexion moment on the knee.

The SPC unit on the medial side of the knee prevents an excessive flexion of the knee during swing and slows down the flexion movement.

The function of the satellite control

Contrary to most control elements for knee hinges, the SPL is provided with a control element that is connected to the hinge by a cable. Apart from mounting on the brace this satellite can also be slid over the waistband. The advantage of this is, that for control one does not have to reach for the knee and in case of bad functioning of the fingers or hand on the side of the orthosis, the satellite can also be controlled/used from the other side.

The satellite determines the function of the pendulum and can put the hinge in three positions:

- fully locked in every position;
- unlock to be able to bend knee with the hip in anteversion;
- automatic lock/unlock.

Patients

The first patient is a male (age 36 years) who had a local resection of a tumour located in the quadriceps muscles of the left leg. During the operation parts of the quadriceps muscles and psoas muscle were resected and the femoral nerve had to be sacrificed. No additional treatment was necessary because of the low tumour activity. Postoperatively the remaining quadriceps muscles were paralysed (MRC scale 0) due to resection of the femoral nerve (Kendall *et al.*, 1971; Medical Research Council, 1975).

The second patient, a male (age 40 years) with muscular dystrophy (Becker's' disease),

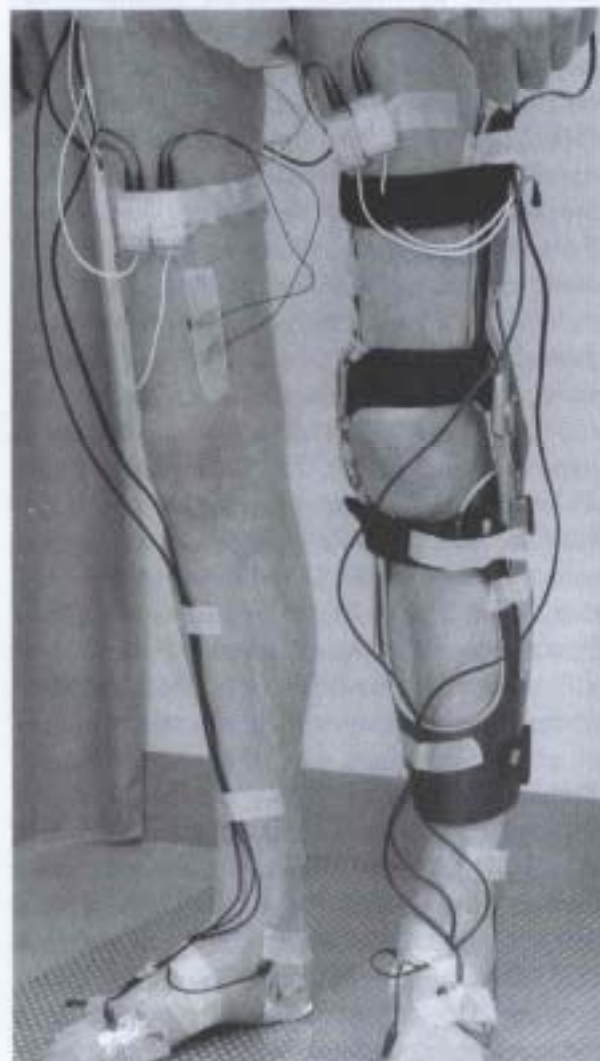


Fig. 2. Hyperextension knee without SPL compared to neutral position of the knee with SPL.

diagnosed and typified when he was 33 years. He was fitted with the SPL because of paresis of the quadriceps muscles on both sides (MRC scale 2). He also had paresis of the hip flexors (MRC scale 4) and hip extensors (MRC scale 4). Without orthosis his maximum walking distance was only 500 metres.

The third patient is a 48-years-old male with a status of two resections of parts of the quadriceps muscles (right side) due to a liposarcoma. The femoral nerve was sacrificed with a paralysis of the quadriceps muscles as a result. Radiotherapy followed.

All three patients were fitted with a knee orthosis with SPL. The SPC unit was not then available, so a free running knee hinge supplemented the SPL.

Instrumented gait analyses

Gait was measured and analysed by "the Walk" gait analysing system using a PC with a 133 MHz processor, sampling at 100Hz. "The Walk" is a software programme that controls the gait measurement. Foot switches at the heel - and toe make it possible to distinguish between stance and swing phase. On both knees, electrogoniometers (Novotechnik, P4101) were placed to measure the angular displacement in the sagittal plane. Standing with straight legs was the position in which 0° of flexion was determined and defined as set point. Surface EMG bipolar electrodes (Red Dot; 3M) were placed on the designated muscles. Electrode placements were in accordance with the recommendations of Perotto (1994). International validated normal data for walking, angles and EMG activity (Winter, 1991; Hof *et al.*, 1999; Hof *et al.*, 2002) were available from the software.

The patients walked several runs on a 7m long straight walkway at their preferred walking speed and wearing their ordinary shoes. Analysis of the gait pattern was carried out by looking at the subsequent projections of knee flexion and EMG activity of each stride. The results of the recorded gait pattern can be compared with available normal data.

Instrumental gait analysis in patients

Patient 1

In walking without the orthosis with the SPL, there is substantial asymmetric gait with a relatively shorter stance-phase at the left side

(involved leg) and a longer stance-phase at the sound side (L/R ratio: 0.78). With the SPL there is less asymmetry (L/R ratio: 0.86). The goniometric data showed persistent hyperextension of the left knee joint during the loading response and mid-stance and diminished knee flexion (30°) in swing-phase. Also the left lower limb showed no active push-off in terminal stance-phase. Wearing the orthosis there was no hyperextension of the left knee joint during the loading response and a normal knee flexion (57°) during swing-phase. The SPL prevented however the normal presence of knee flexion during loading response. No changes were observed at the sound side.

EMG data of the hip extensors showed no substantial differences between walking with or without the orthosis with SPL.

Patient 2

The second patient showed no asymmetric gait. The dystrophic muscle changes had affected both legs in a similar way. To stabilise during initial contact and early stance-phase both knee-joints were locked in hyperextension (8-11°) in terminal swing-phase. At both sides hyperextension remained till pre-swing in which hip flexion and knee flexion initiated swing. During swing-phase there was also slightly diminished knee flexion at both sides (left: 42°, right: 47°). Wearing the orthosis at the left side no hyperextension (0°) occurred during terminal swing and stance-phase (Fig. 3). The right leg (no orthosis) showed also a decreased hyperextension (3-5°). There was a fluent start of knee flexion in pre-swing at both sides and knee flexion was increased to normal at both sides (left: 64°, right: 57°) in swing-phase. EMG data on both sides of knee extensors and knee flexors/hip extensors showed no significant differences between walking with the orthosis compared to walking without this device.

Patient 3

Despite paralysis of the quadriceps muscles of the right leg this patient has no substantial asymmetric gait according to the temporal data. The left/right ratio of the stance-phase duration is 1.03. Wearing the orthosis, a slight asymmetry was introduced; the duration of stance-phase at the orthosis side has increased (L/R ratio: 0.92). Also in this patient, the orthosis prevented hyperextension during early stance-phase at the

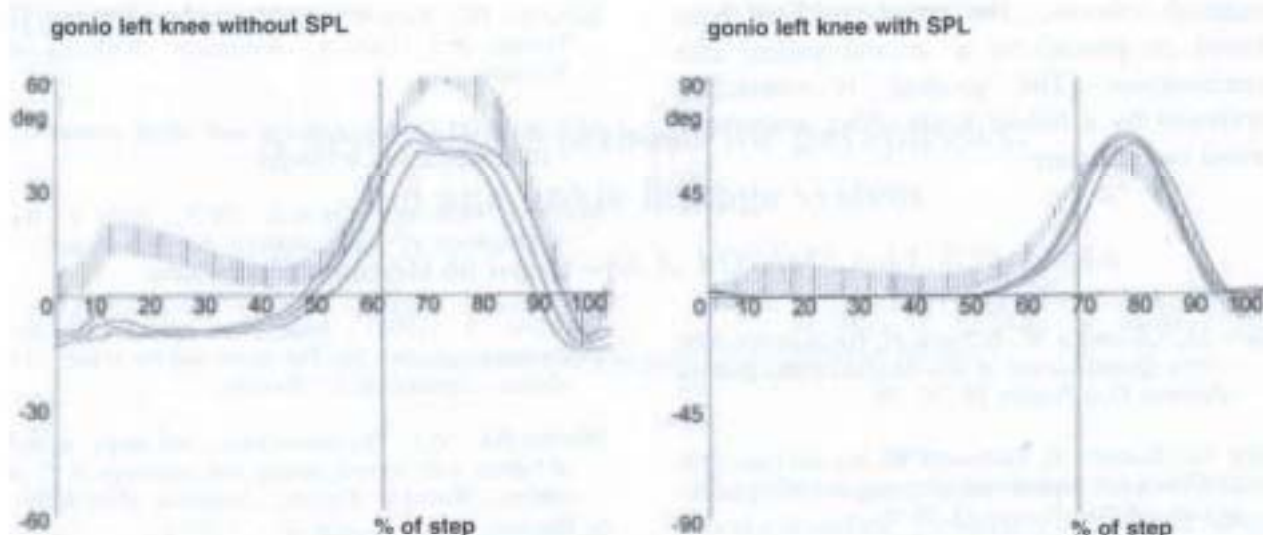


Fig. 3. Goniometric data of patient 2.

Shaded: normal goniometry data of a knee

Lines: goniometry data patient 2 (middle line are the mean data)

SPL means Swing Phase Lock

Deg means degrees

involved side. There was a smooth transition of stance-phase to pre-swing to swing-phase. Without the orthosis, EMG data showed at the right side an increased contraction activity of the semitendinosus muscle and biceps femoris muscle to lock the knee in extension during early stance. With the orthosis with SPL the contraction activity of both muscles was decreased by about 50%. EMG data of other muscles (vastus medialis and lateralis muscles both sides and semitendinosus muscle and biceps femoris muscle) showed no significant differences.

Discussion

All three patients were satisfied with the orthosis with SPL. They all could walk with this new orthosis allowing free knee flexion during swing phase. Instrumented gait analysis showed improvement in gait. Wearing the orthosis, no hyperextension occurred during late swing and stance phase in all three patients. This is clinically relevant because many patients use the compensation mechanism of hyperextension to obtain stability in stance; they are predicted to have knee joint problems after several years. (Cumulative recurrent microtrauma damages the articular cartilage; subchondral bone and the posterior tissues of the capsule and ligaments, leading to chronic instability of the knee joint (McCarty, 1985)). The knee hinge prevented this compensation mechanism as well as the unwanted knee flexion in early stance. Stability

in early stance was acquired by the locking mechanism of the SPL. Reliable extension of the orthosis at the end of the swing phase is essential to obtain this hinge lock. It is therefore essential to train patients to have full extension of the knee in late swing phase. Free flexion of the knee during late stance and swing was possible by the automatic unlocking of the SPL. This unlock mechanism will only work when there is sufficient hip extension and no weight bearing flexion moment on the knee. This was the hardest part for the patient to learn. In the beginning undesired persistent locking of the knee hinge occurred during late stance phase and pre-swing. This required some training sessions to adjust to the new situation (wearing the orthosis). All three patients learned to rely on the orthosis with SPL.

In conclusion a new hinge mechanism is introduced. The swing phase lock provides free flexion of the knee during swing phase and secures locking during stance phase. Medical indications are syndromes accompanied by paresis or paralysis of the quadriceps muscles. Main contraindications are substantial flexion contractures of hip and/or knee. This new device delivers what the name promises.

Addendum

The Swing Phase Lock knee joint has been tested according to the CE Medical Device Directive NEN-EN 1441 (Risk analysis) and NEN-EN 12523 (External limb prostheses and

external orthoses). The prototypes have been tested on patients in a secured patient safe environment. The product is constantly reviewed by a failure mode effect analysis to avoid future failure.

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